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TITLE: Evaluating a novel sleep-focused mind-body rehabilitative program for Veterans with mTBI and other “polytrauma” symptoms: An RCT study

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14. ABSTRACT We obtained IRB approval for the study from the University of Utah IRB, VA SLC HCS and DoD HRPO and we have been preparing to start recruiting study participants for the study.						
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Annual Report

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4. Introduction

The objective of the study is to evaluate and compare the clinical benefit of two sleep-focused therapeutic interventions: Mind-Body Bridging (MBB) and Supportive Education (SED) on disturbed sleep and comorbid symptoms in Veterans with mild Traumatic Brain Injury (mTBI). We will recruit 142 OEF/OIF veterans with mTBI, who first will undergo comprehensive medical and psychological evaluations and then will be randomly assigned to one of the two programs (MBB or SED). Each veteran will receive a total of 6 hours of treatment, in 2-hour sessions once a week over 3 consecutive weeks. Each Veteran will be evaluated again after treatment has been completed. Three months after treatment ends, patients will have another evaluation. Six months after treatment ends, patients will complete follow-up questionnaires. These assessments will help us to evaluate both the efficacy of the therapy programs and any differences in individual treatment response. Additionally, the project will explore underlying mechanisms of action involved in treatment benefits resulting from MBB and SED by using heart rate variability and a biomarker of stress as proxy indicators of intermediate mechanisms presumably activated by MBB and SED.

5. Body

We obtained approval for the study from the University of Utah IRB, VA SLC HCS and DoD HRPO and started planning study logistics and refined them by meeting with the Polytrauma clinic to inform their personnel about the study and to obtain the Polytrauma clinic TBI database to start contacting Veterans.

We also started the process to hire project staffers, including personnel to conduct the medical and psychological evaluations (physician's assistant, psychologists) and MBB and sleep control group instructors.

Other tasks accomplished during Year 1 include putting together the sleep control program, purchasing motion detection device and setting up online survey (REDCap).

6. Key Research Accomplishments

- Obtained approval from the UU IRB, VASLCHCS and DoD HRPO
- Started planning study logistics
- Obtained database with Veterans' contact information
- Started hiring staffers
- Put together the sleep control program
- Purchased motion detection device
- Setting up online survey (REDCap)

7. Reportable Outcomes

We have not started recruiting the study participants as of Sep. 30, 2013, and thus we do not have any result yet to report here.

8. Conclusions

We have not started recruiting the study participants. We are currently not in a position to reach any conclusion regarding study aims and hypothesized benefits of the experimental intervention program (MBB) at the end of Year 1.

9. References

None

10. Appendices

None

11. Supporting Data

None